

### REMARKS

This amendment is in response to the Office action dated October 2, 2006. In the Office action claims 1-18 and 30-33 are rejected. Applicant has amended claims 1, 2, 10, 17, 18, and 30 and added new claims 34-40. Support for the amendments to claim 1, 2, 10, 17, 18, and 30 and new claims 34-40 can be found, for example, at page 10, line 16 – page 11, line 13, page 12, lines 1-5, and Figs. 4 and 5. Claims 1-18 and 30-40 are presented for examination, of which, claims 1, 12, 30 and 34 are independent in form. No new matter has been added.

Applicants acknowledge the election of alternative Species II depicted in Figure 4, wherein magnetic material is applied to less than the entire stent.

Applicants have amended the specification in accordance with the Examiner's recommendation and request that the objection to the specification be withdrawn.

Claims 1, 7, 9, and 10 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,361,759 to Frayne. As amended, claims 1, 7, 9, and 10 require an implantable medical device comprising: a support structure formed such that magnetic field changes in a region immediately proximate the support structure, induced by a magnetic resonance imaging process, are substantially unobstructed by the support structure; and a magnetic material is at least embedded into at least a part of the support structure.

Frayne does not disclose or suggest the claimed subject matter as amended. Instead, Frayne discloses coating a medical device with a polymeric material, the polymeric material includes at least a polymer, an amino group, a chelate, and a paramagnetic material. Indeed, Frayne expressly teaches away from embedding the metal substrate with magnetic material, instead teaching that metallic materials may be treated with coatings of a polymer and then soaked in a solution to allow the paramagnetic ion to react with the polymer coating. (See Frayne, Col. 8, lines 4-14 and 48-55). Therefore, Frayne does not disclose or suggest a magnetic material at least embedded into at least a part of the support structure as required by the amended claims. In light of the above amendment, Applicant's request the rejection be withdrawn.

With regard to claim 10, the Examiner rejected claim 10 under 35 U.S.C. § 102(b) as anticipated by Frayne, asserting that it is inherent that the magnetic material is applied to the end portion because it is applied to the entire structure in order to visualize the entire device.

Applicants note that in order to rely on inherency, “the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.”<sup>1</sup> “Inherency may not be established by probabilities or possibilities.”<sup>2</sup> “The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.”<sup>3</sup>

Furthermore, Frayne argues that visualization of only discrete point(s) of the device , i.e. less than an entire stent, “is a significant limitation for tracking flexible devices as in endovascular therapy.” (See Frayne, Col. 2, Lines 46-56.) Applicants request that the rejection be reconsidered and withdrawn.

Claims 1-3, 5-6, 12, 14, and 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Pub. No. 2003/0100830 to Zhong. As amended, claims 1-3 and 5-6 require an implantable medical device comprising: a support structure formed such that magnetic field changes in a region immediately proximate the support structure, induced by a magnetic resonance imaging process, are substantially unobstructed by the support structure; and a magnetic material at least embedded into at least a part of the support structure.

Zhong does not disclose or suggest the claimed subject matter as amended. Similar to the teaching of Frayne discussed above, Zhong teaches the use of a polymeric coating over the medical device. More specifically, Zhong teaches the use of a hydrogel polymer adapted to incorporate a paramagnetic material within the hydrogel polymer and applied as a coating on an implantable medical device. (Zhong, ¶53; see also Zhong, ¶¶ 26, 29, and 46). Therefore, Zhong does not teach or suggest embedding the magnetic material into the substrate as claimed.

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<sup>1</sup> MPEP § 2112, citing Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

<sup>2</sup> MPEP § 2112, citing In re Roberston, 169 F.3d 743, 745 (Fed. Cir. 1999).

<sup>3</sup> MPEP § 2112, citing In re Rijckaert, 9 F. 3d 1531, 1534 (Fed. Cir. 1993).

With regard to claims 12, 14, and 16-18, Applicants acknowledge the Examiner's comment that such claims invoke 112 ¶ 6. Claims 12, 14 and 16-18 require means for rendering the tubular structure visible during a magnetic resonance imaging procedure. The current application teaches that magnetic material is deposited on top of or embedded into the tubular structure or both to make the tubular structure visible during an MRI procedure. Suitable methods of embedding the magnetic material include plasma immersion ion implantation (PIII) or crimping. (See page 10, lines 16-29). Indeed, when PIII is used, positive ions of the magnetic material strike the surface of the stent and are embedded into or deposited onto the stent surface. (See page 11, lines 11-13). As discussed above, and in the Examiner's own statement in ¶7 of the Office Action, Zhong discloses coating the structure with a hydrogel polymeric material adapted to include a paramagnetic material, not at least embedding magnetic material into the structure. Therefore, Applicants request that the rejection with regard to claims 12, 14, and 16-18 be reconsidered and withdrawn.

With regard to claims 17 and 18, the Examiner rejected claims 17 under 35 U.S.C. §102(b) as anticipated by Zhong, asserting that it is inherent that the magnetic material is applied to the end portion because it is applied to the entire structure in order to visualize the entire device. However, Zhong does not teach or suggest a stent wherein the means for rendering is applied only to the at least one end portion, as now recited in claim 17, or is applied only to the first end portion and the second end portion, as now recited in claim 18. Applicants request that the rejection be reconsidered and withdrawn.

Claim 11 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zhong. Claims 8 and 15 are rejected under 103(a) as being unpatentable over Zhong. But Claims 8 and 11 are dependent on claim 1 as amended and require, inter alia, a magnetic material at least embedded into at least a part of the support structure. Claim 15 is dependent on claim 12 and incorporates all the limitations thereof. For the reasons discussed above, Zhong does not disclose or suggest the claimed subject matter as amended, but instead teaches coating an implantable medical device with a hydrogel polymeric material. Applicants request the rejection be withdrawn.

Claims 4 and 13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Zhong in view of U.S. Patent No. 6,921,414 to Klumb. Claim 4 is dependent on claim 1 as amended and claim 13 is dependent on claim 12 including all the limitations thereof. Zhong in view of Klumb, however, does not disclose or suggest the claimed subject matter. As discussed above, Zhong teaches coating a stent with a hydrogel polymeric material adapted to include paramagnetic material. Klumb does not overcome the deficiencies of Zhong. Applicants request the rejection be withdrawn.

Claims 30-33 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Klumb et al. in view of Zhong et al. Claim 30 requires an elongated medical instrument comprising: a support structure including a segment of material helically oriented about an axis of the instrument wherein the material is at least one of a polymer and a ceramic; and a magnetic material embedded onto the segment. As discussed above, neither Klumb nor Zhong disclose or suggests at least embedding of magnetic material into the support structure or stent, as claimed. Applicants requests the rejection be withdrawn.

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Respectfully submitted,

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